: 4160-90-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on The Effect of Protein Intake on Health

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for Supplemental Evidence and Data Submissions.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review on *The Effect of Protein Intake on Health,* which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES:

E-mail submissions: epc@ahrq.hhs.gov

Print submissions:

Mailing Address:

Center for Evidence and Practice Improvement

Agency for Healthcare Research and Quality

ATTN: EPC SEADs Coordinator

5600 Fishers Lane

Mail Stop 06E53A

Rockville, MD 20857

Shipping Address (FedEx, UPS, etc.):

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Agency for Healthcare Research and Quality

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5600 Fishers Lane

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Rockville, MD 20857

FOR FURTHER INFORMATION CONTACT: Kelly Carper, Telephone: 301-427-1656 or Email: epc@ahrq.hhs.gov.

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for *The Effect of Protein Intake on Health.* AHRQ is conducting this systematic review pursuant to Section 902 of the Public Health Service Act, 42 U.S.C. 299a.

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (e.g., details of studies conducted). We are looking for studies that report on The Effect of Protein Intake on Health*,* including those that describe adverse events. The entire research protocol is available online at: https://effectivehealthcare.ahrq.gov/products/effect-protein-intake/protocol

This is to notify the public that the EPC Program would find the following information on The Effect of Protein Intake on Health helpful:

- A list of completed studies that your organization has sponsored for this indication. In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number*.
    - *For completed studies that do not have results on ClinicalTrials.gov*, a summary, including the following elements: study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline

characteristics, number of patients screened /eligible /enrolled /lost to follow-up /withdrawn /analyzed, effectiveness/efficacy, and safety results.

- *A list of ongoing studies that your organization has sponsored for this indication*. In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.
- Description of whether the above studies constitute *ALL Phase II and above clinical trials* sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution is very beneficial to the Program. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the e-mail list at: https://www.effectivehealthcare.ahrq.gov/email-updates.

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.

Key Questions (KQ)

KQ 1: What is the association between dietary protein intake and risk of bone disease?

KQ 2: What is the association between dietary protein intake and risk of kidney disease?

KQ 3: What is the association between dietary protein intake and risk of sarcopenia?

Population, Intervention, Comparator, Outcome, Timing, Setting/Study Design (PICOTS)

Element	Inclusion	Exclusion
Population KQ1	Participants who are healthy and/or have chronic diseases or chronic disease risk factors, including those with obesity. Participants who are pregnant and lactating Age of participants (at intervention or exposure): ○ Infants, children, and adolescents (0-18 years) ○ Adults (19-64 years) ○ Older adults (65 years and older)	Participants sample exclusively diagnosed with a disease or hospitalized or in a long-term care facility with an illness or injury Participants who have already been diagnosed with bone disease Participants with existing conditions that clearly are known to alter nutrient metabolism or requirements, or those being treated with medications that alter nutrient metabolism Participant sample exclusively undernourished Participant sample exclusively with a baseline diet deficient in protein Participant sample exclusively pre-term infant Participant sample exclusively post-bariatric surgery subjects Participant sample exclusively elite athletes Non-human participants (e.g., animal studies, in-vitro models)
Population KQ2&3	Participants who are healthy and/or have chronic diseases or chronic disease risk factors, including those with obesity. Participants who are pregnant and lactating Age of participants (at intervention or exposure): ○ Adults (19-64 years) ○ Older adults (65 years and older)	Participants sample exclusively diagnosed with a disease or hospitalized or in a long-term care facility with an illness or injury Participants who have already been diagnosed with kidney disease and/or sarcopenia Participants with existing conditions that clearly are known to alter nutrient metabolism or requirements, or those being

		treated with medications that alter nutrient metabolism Participant sample exclusively undernourished Participant sample exclusively with a baseline diet deficient in protein Participant sample exclusively post-bariatric surgery subjects Participant sample exclusively elite athletes Non-human participants (e.g., animal studies, in-vitro models)
Interventions KQ1-3	Total dietary protein intake from food, beverages, and dietary supplements	No specification on the amount of protein intake (e.g., only the type of protein or source of protein reported) Assessment of %AMDR, but no description of the entire macronutrient distribution of the diet (i.e., examination a single macronutrient in relation to outcomes) Protein intake via infusions (rather than the GI tract) Food products or dietary supplements not widely available to U.S. consumers Protein intake evaluated with exercise
Comparison KQ1-3	• Consumption of different levels of total dietary protein intake • No comparator	Comparison of different sources of protein (i.e., animal versus plant protein) without specification on the levels of total dietary protein intake
Outcomes KQ1	Bone outcomes: ○ Osteoporosis ○ Osteopenia ○ Fracture ○ Bone mass including bone mineral density, bone mineral content	
Outcomes KQ2	Kidney outcomes: ○ Incidence of kidney stones or ureteral stones ○ Incidence of CKD (including evaluations from estimated glomerular filtration (eGFR) rate with or without a parameter for race)	

	○ Kidney insufficiency	
Outcomes KQ3	Aging associated sarcopenia and its diagnostic indicators, including but not limited to muscle mass, muscle function, muscle strength	
Timing KQ1-3	All duration and follow up	
Setting KQ1-3	All settings	
Study design KQ1-3	• Randomized controlled trials (RCTs) • Non-randomized controlled trials, including quasi-experimental and controlled before-and-after studies • Prospective cohort studies with or without comparison group with appropriate analytic technique • Nested case-control studies	• Narrative reviews • Systematic reviews, meta-analyses, umbrella reviews, scoping reviews • Systematic reviews or meta-analyses that exclusively include cross-sectional and/or uncontrolled studies • Retrospective cohort studies • All other study designs
Language KQ1-3	English only (due to resource limitations)	
Geographic Location KQ1-3	Locations with food products or dietary supplements widely available to U.S. consumers, including those rated very high on the Human Development Index	
Study size KQ1-3		Studies with N < 50 participants (for RCTs - 25 participants analyzed per study arm), and without power calculation
Publication date KQ1-3	2000 to present	
Publication status KQ1-3	Articles published in peer-reviewed journals	Articles that have not been peer reviewed and are not published in peer-reviewed journals (e.g., unpublished data, manuscripts, pre-prints, reports, abstracts, conference proceedings)

Abbreviations: AMDR=Acceptable macronutrient distribution range; GI=gastrointestinal; U.S.=United States; KQ=key question; CKD=chronic kidney disease; eGFR=estimated glomerular filtration rate; RCT=randomized controlled trial

Dated: June 8, 2023.

Marquita Cullom,

Associate Director.

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